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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,243	12/21/2001	Richard S. Judson	2458-4042US3	3139

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GENAISSANCE PHARMACEUTICALS
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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,243	JUDSON ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-21,74-78 and 125-129* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-21,74-78 and 125-129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 12/21/01 cancels claims 1-12, 22-73, 79-124, and 130-183. Claims 13-21, 74-78, and 125-129 are under consideration by the examiner.

Priority

The petition granted 9/16/02 converts the instant application from an application filed under 35 USC 371 to an application filed under 35 USC 111(a). The instant application has been given a filing date of 12/21/01. As PCT/US00/17540 designated the United States, the instant application is considered to be a continuation of PCT/US00/17540, filed 6/26/00, which claims priority to provisional application 60/141,521, filed 6/25/99.

The first page of the specification should be amended to reflect applicant's priority claim and the relationship between the various applications.

Inventorship

In view of the papers filed 11/4/03, the inventorship in this nonprovisional application has been changed by the deletion of inventors R. Rex Denton, Guablerto Ruano, and J. Claiborne Stephens. The inventors are Richard S. Judson, Andreas K. Windemuth, and Chuanbo Xu.

Information Disclosure Statement

The information disclosure statements submitted 6/12/03, 7/27/04, 8/18/04, and 10/21/04 are noted.

Claim Rejections - 35 USC § 112

Claims 13-21, 74-78, and 125-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 13-21 are directed to methods of identifying a correlation between a haplotype pair and a clinical response to a treatment.

Claims 74-78 are directed to computer-usable media having computer-readable program code stored thereon. The computer-readable code essentially executes the methods of claims 13-21.

Claims 125-129 are directed to computers programmed to identify a correlation between a haplotype pair and a clinical response to a treatment. The computers are programmed essentially to execute the methods of claims 13-21.

The specification does not enable methods with respect to the "other phenotype" limitations of the claims. The specification does not provide guidance on selecting a candidate locus hypothesized to be associated with phenotypes such as IQ, degree of hair curl, height, weight, and so forth. It is unclear whether such a database exists containing the breadth of information the claims embrace. Note also that the claims require that the locus selected comprise at least two polymorphic sites.

For the embodiments limited to clinical outcome, the claims require haplotype data for each member of the clinical population and a database containing data on clinical responses to treatment. These methods are not enabled.

For example, suppose the clinical population had 2 subjects. Suppose each subject had a unique haplotype and each subject had different clinical response or outcome data. For example, the information for subject A was had a migraine, took Advil, pain was ameliorated and the

information for subject B was terminal cancer, radiation therapy unsuccessful. The specification does not teach how to practice the method with this information nor what meaningful information might be expected to be extracted. The claims don't speak to size or composition of the clinical population such that statistically valid results are produced, comparison of like information, and so forth. Note that only claim 20 regards statistical significant of the correlation. With respect to claim 21, the relationship between the clinical population and the reference population is not specified such that one could make the inference of an individual's haplotype pair with any confidence. That is, the clinical population could be rabbits and the reference population could be humans or the clinical population could be patients with diabetes and reference population could be patients with melanoma.

Finally, the specification discloses no databases readily available to the public containing the information required by the claims. It is considered to be undue experimentation to produce such a database as it would require one of ordinary skill in the art to exercise inventive skill and judgment in determining what information to include and exclude and in what form to compile the information decided upon for statistical analysis.

Claims 13-21, 74-78, and 125-129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is directed to a method for identifying a "correlation between a haplotype pair and a clinical response to a treatment, or other phenotype." Part (a) recites "clinical responses to treatments, or other phenotypes." It appears that the intent is a correlation between a haplotype

pair and a clinical response to a treatment or a correlation between a haplotype pair and a phenotype, but the language of the claim makes this confusing as to the goal and the steps to be performed. See also claims 74 and 125 that use similar language.

The preamble of claim 13 requires identifying a correlation whereas the final step requires calculating the degree of correlation. This inconsistency is confusing. The method has been interpreted as being directed to a method where a correlation is actually found. If no correlation is found or the correlation found is not statistically significant (see claim 20), then the method would not produce a concrete, tangible, and useful result and be subject to a rejection under 35 USC 101 as being non-statutory. In addition, one of ordinary skill in the art would not know how to use the results of the method consistent with 35 USC 112 in the absence of a statistically significant correlation. Clarification is requested.

Claim 14 is confusing in that step (e) by the nature of the method must be performed last and as such this does not appear to further limit claim 13. That is, the calculation cannot be performed until the clinical response data and haplotype data are obtained.

With respect to claim 18 it cannot be determined what the metes and bounds of a "gene feature" are.

Claims 74-78 and 125-129 are unclear as to whether each portion of computer-readable program code (i.e. (a) through (h)) are a sections of a single program, separate programs, or something else. The claims don't make clear any relationship between the program code of the subparts. For example, it is unclear if the code must be executed sequentially, in a particular order, in any order, or that output from one part of code is used as input to another part of the

code. It appears that the outcome of some portions of the code are intended to be used as input for other portions of the code, but the claims do not make this clear.

Claims 75-76 do not clearly modify the computer-usable medium of claim 74. The type of treatment or identity of the candidate locus would not appear to alter the program code in any way. That is, locus X has not been disclosed in the specification as requiring unique code that differs from locus Y. For the same reasons, claims 126-127 do not clearly modify the computer programmed in claim 125. The structure and function of the computer remains the same.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 13-21, 74-78, and 125-129 are rejected under 35 U.S.C. 102(a) as being anticipated by Layton et al. (Rheumatology, January 1999).

Layton et al. discloses determining a correlation between therapeutic response to D-penicillamine in rheumatoid arthritis with respect to genotype and haplotype of the glutathione S-transferase (GST) supergene family. (See at least abstract, section on Patients and Methods, and Tables 1-2.) The method of Layton et al. was performed using a computer and graphically displayed. A computer-usable medium meeting the limitations of claims 74-78 and a programmed computer meeting the limitations of claims 125-129 are disclosed by Layton et al. With respect to claims 15-16, clinical data was collected before and after steps (b), (c), and (d) for the various clinical populations included in the analysis.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Marianne P. Allen
Primary Examiner 3/18/05
Art Unit 1631

mpa